

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 11985

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-138-5	Methamphetamine Mandelate Tablets 0.25 gr. E.C.	1	Richlyn Labs., Inc. (MFR. & RECALLER) Philadelphia, Pa. (Dist. under Richlyn Labs. label & the following private labels: Spencer Mead Valley Stream, N.Y. Mellins Melville, N.Y. Robinson Labs. San Francisco, Ca.)	Product failed USP disintegration tests conducted by the manufacturer.	Vol.	II	Rx
D-139-5	Septi-Phene Presurgical Soap USP liquid concentrate 28	5	Pan Western Trading Corp. Inglewood, Ca. (RECALLER)	Labels of the product declare HCP, but the product does not contain HCP.	Vol.	II	Rx
D-140-5	Big-Sol	5	Pan Western Trading Corp. Inglewood, Ca. (RECALLER)	Labels of the product declare HCP, but the product does not contain HCP.	Vol.	II	Rx
D-143-5	Digitoxin 0.1 mg. 100, 500, 1000, & 5000's tablet bottles	1	Westerfield Labs., Inc. Cincinnati, Ohio	Product failed content uniformity requirements	Vol.	II	Rx
D-145-5	Liquid Lytren Oral Electrolyte Solution for Oral Use Only (Ready-to-use solution with Beniflox disposable Nurse 32 fl. oz.)	SND-17 followed by the letters A-W representing 13 retort loads	Mead Johnson Labs. (MFR) Bellville, Ontario, Canada Mead Johnson & Co. Evansville, Ind. (RECALLER)	Bacteriological contamination	Vol.	I	OTC Hospital use only - not for retail outlets.
D-146-5	QID Pen V-K (Potassium phenoxymethyl penicillin USP) 250 mg. (400,000 units) per 5 ml. in 100 ml. bottles	1	Mylan Pharmaceutical Inc. Morgantown, W. Va.	Mislabeled - label declares 250 mg./5 ml. - bottles contain 125 mg./5 ml.	Vol.	II	Rx
D-147-5	Disoxin Tablets 0.25 mg.	1	American Pharmaceutical Co. Bronx, N.Y. (MFR) Daylin Medical Inc. Los Angeles, Ca. (RECALLER)	Product failed USP dissolution test and requirements set forth in the FR 1/22/74	FDA Init.	II	Rx